

10/533325

JC17 Rec'd PCT/PTO 02 MAY 2005

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Claims**

1. (original) A pharmaceutical composition comprising:
  - i) a controlled release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof; and
  - ii) an immediate release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof and (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof.
2. (original) A pharmaceutical composition comprising:
  - i) one layer containing a controlled release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof; and
  - ii) a second layer containing an immediate release formulation of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof and 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof.
3. (currently amended) A pharmaceutical composition according to claim 1 ~~or 2~~ wherein the controlled release formulation releases 3'-azido-3'-deoxythymidine within 3 - 6 hours.
4. (currently amended) A pharmaceutical composition according to ~~any of claims 1 - 3~~ claim 1 wherein the controlled release formulation comprises a mixture of polymers.

5. (original) A pharmaceutical composition according to claim 4 wherein the polymers are hydroxypropylmethylcellulose.
6. (currently amended) A pharmaceutical composition according to claim 1 ~~any of claims 1—5~~ wherein the amount of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is from about 150 to about 450 mg per unit dosage form.
7. (currently amended) A pharmaceutical composition according to claim 1 ~~any of claims 1—5~~ wherein the amount of 3'-azido-3'-deoxythymidine is from about 100 to about 750 mg per unit dosage form.
8. (currently amended) The pharmaceutical composition according to ~~any of claims 1—6~~ claim 1 wherein (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is provided substantially free of the corresponding (+)-enantiomer.
9. (currently amended) The pharmaceutical composition according to ~~any of claims 1—6~~ claim 1 wherein (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is provided such that the corresponding (+)-enantiomer is present in an amount of not more than about 5% w/w of the amount of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one.
10. (currently amended) A pharmaceutical composition according to ~~any of claims 1—9~~ claim 1 for once daily administration.
11. (currently amended) A pharmaceutical composition according to ~~any of claims 1—9~~ claim 1 in the form of a bilayer tablet or multilayer tablet.
12. (currently amended) A pharmaceutical composition according to ~~any of claims 1—9~~ claim 1 in the form of a bilayer tablet.
13. (currently amended) A pharmaceutical composition according to ~~any of claims 1—9~~ claim 1 in the form of a tablet within a tablet.

14. (currently amended) A method for the treatment or prevention of an HIV infection in a mammal comprising administering a pharmaceutical composition according to ~~any of claims 1-13~~ claim 1.

15. (new) A pharmaceutical composition comprising:

- i) a controlled release formulation of 3'-azido-3'-deoxythymidine;  
and
- ii) an immediate release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof and (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one.

16. (new) A pharmaceutical composition according to claim 1 wherein the pharmaceutically acceptable derivative of 3'-azido-3'-deoxythymidine is a salt thereof and the pharmaceutically acceptable derivative of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is a salt thereof.

17. (new) A pharmaceutical composition according to claim 16 wherein the salt of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is a mesylate salt.